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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 10/767,352 | MAURER ET AL. | |
| | Examiner | Art Unit | |
| | BLESSING M. FUBARA | 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/14/2010.
2. ☒ The allowed claim(s) is/are 2-9, 13 and 15-23 (claims are renumbered).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>4/27/2010</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618

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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Shawna Cannon Lemon on 4/27/2010 and 5/10/2010.

The application has been amended as follows:

In claim 6, line 1, replace "an" with---a--- and after "an" replace " a_w " with ---water activity (a_w) of---

In claim 15, after "humectant" add

---, wherein said hyperproliferative disorders are selected from the group consisting of tumors, cancers, neoplastic tissue, premalignant, non-neoplastic and non-malignant hyperproliferative disorders:

i) the tumors, cancers and neoplastic tissues are selected from the group consisting of breast cancers; osteosarcomas; angiosarcomas; fibrosarcomas; leukemias; lymphomas; sinus tumors; ovarian, uretal, bladder, prostate; colon, esophageal, stomach cancers; lung cancers; myelomas; pancreatic cancers; liver cancers; kidney cancers; endocrine cancers; skin cancers; and brain or central and peripheral nervous (CNS) system tumors, malignant or benign gliomas and neuroblastomas,

ii) the premalignant, non-neoplastic or non-malignant hyperproliferative disorders are selected from the group consisting of myelodysplastic disorders; cervical carcinoma-in-situ;

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Gardner syndrome, a familial intestinal polyposis; oral leukoplakias; histiocytoses; keloids; hemangiomas; hyperproliferative arterial stenosis, inflammatory arthritis; hyperkeratoses, arthritis that is a papulosquamous eruptions; and warts, infectious mononucleosis and scar formation that are viral induced hyperproliferative diseases---

Claims 6 and 15 as amended are listed below:

Claim 6 (Currently amended) The method of claim 15, said composition having a[an] water activity (a_w) of[a_w] less than 0.85.

Claim 15 (Currently amended) A method of treating a hyperproliferative disorder in a subject in need thereof, comprising feeding said subject an amount effective to treat said hyperproliferative disorder of an edible composition for delivery of a retinide, said composition comprising a dry flowable powder, the dry flowable powder comprising:

(a) from 1 to 10 percent by weight of retinide;

(D) from 5 to 40 percent by weight of non-acidic lipid matrix composition, said matrix composition comprising at least one fatty acid, at least one monoglyceride, and lysophosphatidylcholine, and said lipid matrix composition containing not more than 4 moles water per mole of lipid matrix;

(c) from 1 to 30 percent by weight of sweetener;

(d) from 20 to 80 percent by weight flour; and

(e) from 0 to 16 percent by weight of a humectant,

wherein said hyperproliferative disorders are:

i) tumors, cancers and neoplastic tissue selected from the group consisting of breast cancers; osteosarcomas; angiosarcomas; fibrosarcomas; leukemias; lymphomas; sinus tumors;

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ovarian, uretal, bladder, prostate; colon, esophageal, stomach cancers; lung cancers; myelomas; pancreatic cancers; liver cancers; kidney cancers; endocrine cancers; skin cancers; and brain or central and peripheral nervous (CNS) system tumors, malignant or benign gliomas and neuroblastomas,

ii) premalignant, non-neoplastic or non-malignant hyperproliferative disorders selected from the group consisting of myelodysplastic disorders; cervical carcinoma-in-situ; Gardner syndrome, a familial intestinal polyposis; oral leukoplakias; histiocytoses; keloids; hemangiomas; hyperproliferative arterial stenosis, inflammatory arthritis; hyperkeratoses, arthritis that is a papulosquamous eruptions; and warts, infectious mononucleosis and scar formation that are viral induced hyperproliferative diseases.

Reasons for Allowance

The examiner is aware of co-pending application 11/170,561. A terminal disclaimer has been filed in 11/170,561 on 4/14/2010.

2. The following is an examiner's statement of reasons for allowance: The primary reason for allowance is the presence of flour and sweetener in the retinide composition fed to a subject in need thereof for treating hyperproliferative disorder. Applicant's declaration filed 1/27/2010 and 4/14/2010 (corrected for serial number) at page 2 and Appendices 2-4 shows that the oral powder produced several fold higher fenretinide plasma levels than fenretinide oral capsules.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618